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In Re: Patent Term Extension
Application for
U.S. Patent No. 4,604,463

#16

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,604,463, which claims the human drug product CAMPTOSAR® (irinotecan hydrochloride), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,141 days. U.S. Patent No. 4,604,463 has an original expiration date of July 5, 2004, subject to the provisions of 35 U.S.C. § 41(b). Accordingly, extension of the patent for 1,141 days will result in an extended expiration date of August 20, 2007.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of January 28, 1997 (62 Fed. Reg. 4066). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1,941) + 170 \\ &= 1,141 \text{ days (3.12 years)}\end{aligned}$$

Since the regulatory review period began September 5, 1990, after the patent issue date (August 5, 1986), the entire period has been considered in the above determination. No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the five year limitation of 35 U.S.C. § 156(g)(6)(A) nor the 14 year limitation of 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of 1,141 days.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

| | | |
|--------------------------|---|----------------|
| U.S. Patent No. | : | 4,604,463 |
| Granted | : | August 5, 1986 |
| Original Expiration Date | : | July 5, 2004 |

| | | |
|------------------------------|---|--|
| Applicant | : | Tadashi Miyasaka et al. |
| Owner of Record | : | Kabushiki Kaisha Yakult Honsha |
| Title | : | Camptothecin Derivatives and Process for Preparing Same |
| Classification | : | 544/125 |
| Product Trade Name | : | CAMPTOSAR® (irinotecan hydrochloride) |
| Term Extended | : | 1,141 days |
| Expiration Date of Extension | : | August 20, 2007 |

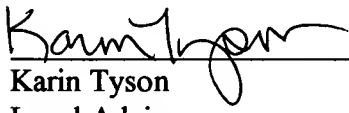
Any correspondence with respect to this matter should be addressed as follows:

By mail: Assistant Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231

By FAX: (703) 308-6916
Attn: Special Program Law Office

By hand: One Crystal Park, Suite 520
2011 Crystal Drive
Arlington, VA

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.


Karin Tyson
Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 15-22
Rockville, MD 20857

RE: CAMPTOSAR®
FDA Docket No.: 96E-0379